K101777 C-1

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:	Medtronic Vascular 3576 Unocal Place Santa Rosa, CA 95403 USA
Contact Person:	Lucinda L. Fox Regulatory Affairs Manager Medtronic Vascular 3576 Unocal place Santa Rosa, CA 95403 Phone: 707.591.7028 Fax: 707.591.7138 lucinda.l.fox@medtronic.com
Date Prepared:	June XX, 2010
Trade Name:	Pioneer Plus Catheter
Common Name:	Diagnostic Ultrasound Transducer and Percutaneous Catheter
Classification Name:	Diagnostic Ultrasound Transducer and Percutaneous Catheter
Predicate Device:	Pioneer Plus Catheter, K081804 (cleared August 5, 2008)
Device Description:	Percutaneous catheter that utilizes IVUS imaging and a hollow Nitinol needle to facilitate redirection and placement of a 0.014" OTW guidewire into peripheral vessels. The guidewire can then facilitate placement of subsequent devices. The device is a single use, sterile catheter.
Statement of Intended Use:	The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTCA, stent, etc.). The Pioneer Plus catheter is not indicated for use in the coronary or cerebral vasculature.
Summary of Technological Characteristics:	The subject and predicate Pioneer Plus Catheters are identical in terms of indications for use, intended use, performance specifications, and material specifications. Both devices are designed to facilitate placement of catheters in the peripheral vasculature and both are sterile, single-use devices with a working length of 120 cm, IVUS capability, and Nitinol needle/guide tip.
Summary of Non-clinical Data:	A Warning and mitigation steps for managing a needle retraction failure were added to the Instructions for Use. The modifications provide additional safety information to clinicians to facilitate safe use of the Pioneer Plus Catheter. The changes are being implemented based on postmarket clinical feedback and are associated with a Field Corrective Action. No changes were made to the intended use or indications for use, nor were changes made to the product's material

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or performance specifications. Manufacturing process improvements were implemented on the needle subassembly to enhance production consistency and insure the product continues to meet its original specifications. Testing on the needle subassembly was completed and confirmed the process changes did not negatively affect its performance or functionality.

Conclusion from Data:

The information above demonstrates equivalence and supports a determination of substantial equivalence between the Subject and Predicate Pioneer Plus Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Vascular
Ms. Lucinda Fox
Regulatory Affairs Manager
3576 Unocal Place
Santa Rosa, CA 95043

SEP 18 2013

Re: K101777
Trade/Device Name: Pioneer Plus Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, ITX
Dated: June 24, 2010
Received: June 25, 2010

Dear Ms. Fox:

This letter corrects our substantially equivalent letter of July 23, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

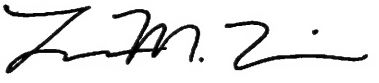
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K101777

Device Name: Pioneer Plus Catheter

Indications for Use:

The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTCA, stent, etc.). The Pioneer Plus catheter is not indicated for use in the coronary or cerebral vasculature.

Prescription Use __X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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